**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

# STATEMENT OF INVESTIGATOR

***(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)***

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: September 30, 2002.
*See OMB statement on reverse.*

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR:

DRUG SHIPMENT ADDRESS AND PHARMACIST DESIGNEE:

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFIES THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ATTACHED.

☐ CURRICULUM VITAE ☐ OTHER STATEMENT OF QUALIFICATIONS

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED.

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES).

6. NAMES OF THE SUBINVESTIGATORS (*e.g., research fellows, residents, and associates*) WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).

N/A

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR.

I am participating in National Cancer Institute sponsored clinical protocols.

IF YOU ARE A MEMBER OF AN NCI COOPERATIVE GROUP, CCOP, MBCCOP, OR CONSORTIUM, PLEASE PROVIDE THE NAME OF THE ORGANIZATION.

8. ATTACH THE FOLLOWING CLINICAL PROTOCOL INFORMATION: * *

1. Check either or both boxes as appropriate.
2. Protocol(s) need not be attached.

☐ FOR PHASE 1 INVESTIGATIONS, A GENERAL OUTLINE OF THE PLANNED INVESTIGATION INCLUDING THE ESTIMATED DURATION OF THE STUDY AND THE MAXIMUM NUMBER OF SUBJECTS THAT WILL BE INVOLVED. * *

☐ FOR PHASE 2 OR 3 INVESTIGATIONS, AN OUTLINE OF THE STUDY PROTOCOL INCLUDING AN APPROXIMATION OF THE NUMBER OF SUBJECTS TO BE TREATED WITH THE DRUG AND THE NUMBER TO BE EMPLOYED AS THE CONTROLS, IF ANY; THE CLINICAL USES TO BE INVESTIGATED; CHARACTERISTICS OF SUBJECTS BY AGE, SEX, AND CONDITION; THE KIND OF CLINICAL OBSERVATIONS AND LABORATORY TESTS TO BE CONDUCTED; THE ESTIMATED DURATION OF THE STUDY; AND COPIES OR A DESCRIPTION OF CASE REPORT FORMS TO BE USED. * *

* * Refer to number item 7 and the NCI Drug Master File #2803 at FDA for a general outline of planned investigation.

9. COMMITMENTS:

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

## INSTRUCTIONS FOR COMPLETING FORM FDA 1572
## STATEMENT OF INVESTIGATOR:

1. Complete all sections. Attach a separate page if additional space is needed.
2. Attach curriculum vitae or other statement of qualifications as described in Section 2.
3. Attach protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND ATTACHMENTS TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an investigational New Drug Application (IND).

| 10. SIGNATURE OF INVESTIGATOR | 11. DATE |
|---|---|
| | |

(**WARNING:** A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

**Public reporting burden for this collection of information** is estimated to average 100 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CBER (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER (HFD-94)
5516 Nicholson Lane
Kensington, MD 20895

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

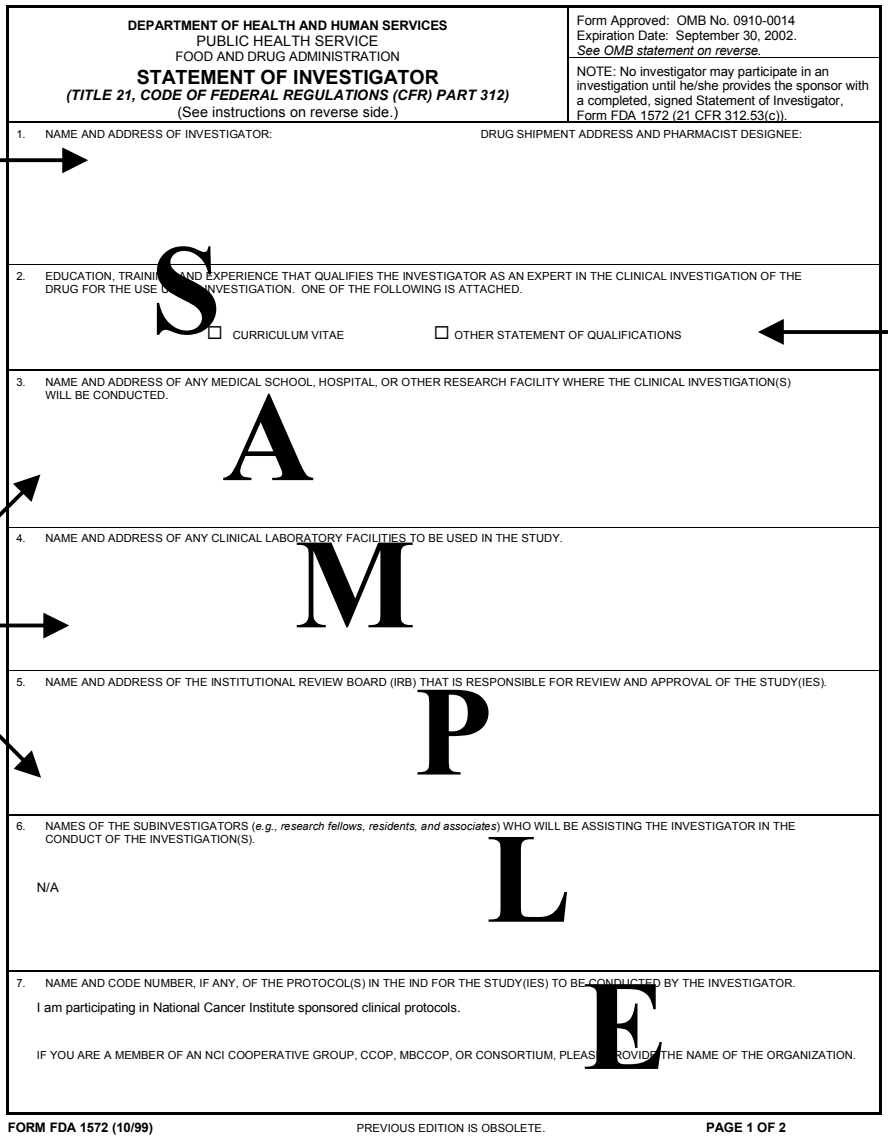
Please DO NOT RETURN this application to this address.

# INSTRUCTIONS FOR COMPLETING STATEMENT OF INVESTIGATOR (FDA 1572 FORM)

Complete the form as indicated and return it to the NCI within six weeks. Use the envelope provided. Please note that the signature and date must be original.

Provide Investigator name, office mailing address, phone and fax numbers (include area code) and e-mail address. Provide the same information for the Pharmacist or Designee and the shipping address for investigational agents.

Provide all relevant information for items 3, 4, and 5. Attach separate pages if necessary.



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**FORM FDA 1572 (10/99)** PREVIOUS EDITION IS OBSOLETE. **PAGE 1 OF 2**



Check one box. Attach your CV (preferred) or other statement of qualifications.

The first part of item 7 has already been completed.

# INSTRUCTIONS FOR FDA 1572 FORM (continued)

Check one or both boxes, as appropriate.

1. ATTACH THE FOLLOWING CLINICAL PROTOCOL INFORMATION: * *

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Read item 9. You do not have to complete any information.

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An original signature is required here. Submit the original of this form, do not send a photocopy.

| 3. SIGNATURE OF INVESTIGATOR | 4. DATE |
|---|---|
| | |

The date of the signature.

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**FORM FDA 1572 (10/99)** **Return Form to: Pharmaceutical Management Branch, Cancer Therapy Evaluation Program** **PAGE 2 OF 2**
**Division of Cancer Treatment and Diagnosis, NCI**
**Executive Plaza North, Room 707**
**9000 Rockville Pike, Bethesda, MD 20892-7422**